K012139

JAN 17 2002

SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

Proprietary Name:	Vamos Anesthetic Gas Monitor
Classification Name:	Analyzer, Gas, Carbon-Dioxide, Gaseous Phase – 73 CCK Analyzer, Gas, Nitrous-Oxide, Gaseous Phase – 73 CBR Analyzer, Gas, Enflurane, Gaseous Phase – 73 CBQ Analyzer, Gas, Halothane, Gaseous Phase – 73 CBS Oximeter – 74 DQA
Device Class:	Class II
Manufacturer:	Dräger Medizintechnik GmbH 53/55 Moislinger Allee Lübeck, Germany 23558
Establishment Registration No.:	9611500
Devices to which substantial equivalence is claimed:	Vitalert 3000 Monitoring System – K913995 NPB4000 Pulse Oximeter – K962424

Device Description:

The Vamos is an integrated monitoring system used for multiple gas analysis (CO_2, N_2O, and anesthetic agent concentrations). Pulse oximetry may also be included as an option.

Intended Use:

The Vamos may be used for measuring and monitoring the functional oxygen saturation (SpO2), pulse rate and the concentrations of CO_2, N_2O and the following anesthestic agents; Halothane, Enflurane, Isoflurane, Sevoflurane, and Desflurane.

Substantial Equivalence:

Like the Vitalert 3000 (VA3000), the Vamos is an integrated monitoring system used for multiple gas analysis (CO_2, N_2O, and anesthetic agent concentrations) and Pulse oximetry. The VA3000 offers Non-Invasive Blood Pressure (NIBP) monitoring as an option while the Vamos does not.

The Vamos and VA3000 integrate the function of the electronic monitors. Measurement data, a real time CO_2 waveform, and alarms are displayed. Both use an electro- luminesoent display.

The Vamos and VA3000 use a combination of a keypad and incremental encoder to control screen formats and settings.

The Vamos offers an optional battery backup system, which is automatically enabled in the event of power failure and provides a one hour minimum power reserve time from full charge. The VA3000 does not have a battery backup system.

The Vamos uses the same pulse oximetry module as the NPB4000 Pulse Oximeter (K962424).

The gas analyzer used in the Vamos is similar to that used in the VA3000 in that both utilize infrared absorption technology.

The Vamos and the VA3000 incorporate an RS-232 serial communication port.

Qualification of the Vamos included hazard analysis, functional, communication, environmental, and electromagnetic compatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 7 2002

Mr. Michael A. Kelhart
Draeger Medical Inc.
3135 Quarry Road
Telford, PA 18969

Re: K012139
Vamos Anesthetic Gas Monitor
Regulation Number: 868.1400, 868.1700, 868.1500, 868.1620, and 870.2700
Regulation Name: Carbon-Dioxide Gas Analyzer, Nitrous-Oxide Gas Analyzer, Enflurane Gas Analyzer, Halothane Gas Analyzer, and Oximeter
Regulatory Class: II (two)
Product Code: 73 CCK, CBR, CBQ, CBS, NHO, NHP, NHQ, and 74 DQA
Dated: October 23, 2001
Received: October 24, 2001

Dear Mr. Kelhart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012139

Device Name: Vamos Anesthetic Gas Monitor

Indications for Use:

The Vamos Variable Anesthetic Gas Monitor is indicated for measuring and monitoring the CO2 concentration, functional oxygen saturation SpO2, pulse rate and the concentrations of N2O, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane. Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012139

(Optional Format 1-2-96)